510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k032382

B. Analyte:
Gemifloxacin (0.001 -16 ug/ml)

C. Type of Test:
Quantitative Antimicrobial Susceptibility Test (AST) growth based fluorescence

D. Applicant:
TREK Diagnostic Systems, Inc.

E. Proprietary and Established Names:
Sensititre® *Haemophilus/Streptococcus pneumoniae* (HP) MIC Plates

F. Regulatory Information:

1. Regulation section:
   866.1640 Antimicrobial Susceptibility Test Powder
2. Classification:
   II
3. Product Code:
   JWY-manual readings of AST testing of >16 hour incubation
   LRG Automated readings of AST of >16 hour incubation.
4. Panel:
   83 Microbiology

G. Intended Use:

1. Intended use(s):
   The Sensititre® *Haemophilus influenzae/Streptococcus pneumoniae* plates are *in vitro* diagnostic products for clinical susceptibility testing of *Haemophilus influenzae*, *Streptococcus pneumoniae* and other fastidious isolates.
2. Indication(s) for use:
   The addition of gemifloxacin in the dilution range of 0.001 -16 ug/ml to the Sensititre® *Haemophilus/Streptococcus pneumoniae* (HP) MIC Susceptibility plate MIC panel is for testing *Haemophilus influenzae* and *Streptococcus pneumoniae* isolates.
3. Special condition for use statement(s):
   S. pneumoniae are diluted in lysed horse blood for a final concentration of 2-5% and the Haemophilus influenzae are diluted in Haemophilus Test Medium (HTM)
4. Special instrument Requirements:
   Not applicable

H. Device Description:
Sensititre® *Haemophilus/Streptococcus pneumoniae* (HP) MIC Susceptibility plate MIC panels are multi-well plastic microtitre plates, precision dosed with dried, stabilized antimicrobics.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Pasco MIC and MIC/ID Panels
2. Predicate K number(s):
   k032259
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	same	same
Inoculum	Prepared from colonies using the direct inoculation method	Prepared from colonies using the direct inoculation method
Inoculation method	Direct equated to a 0.5 McFarland	Direct equated to a 0.5 McFarland
Incubation	18-24 hours	18-24 hours
Item	**Device**	**Predicate**
Type panel	Dried antibiotics	100 µl/well frozen
Technology	Fluorescence detection of growth	Turbidity detection of growth
Reading method	Visual growth and Auto read by instrumentation	Visual growth

J. Standard/Guidance Document Referenced (if applicable):
"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; NCCLS M7 (M100-S13) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard"

K. Test Principle:
The Sensititre Autoread System utilizes fluorescence technology to read 18-24 hour plates. The Sensititre manual system for MIC's is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     Reproducibility testing was performed at only two sites following a very old version of the AST guidance document. Ten *S. pneumoniae* and 10 *H. influenzae* were tested three times at each site. All isolates had on scale results at all times. The *S. pneumoniae* readings were done both manually and by the Autoread method. All studies had acceptable results with one site having a slight trend to a one well more susceptible result with the Autoreader.
   - *b. Linearity/assay reportable range:*
     Not applicable
   - *c. Traceability (controls, calibrators, or method):*

ORGANISM	**Conc ug/ml**	**Reference**	**Sensititre® Auto**	**Sensititre® manual**
S. pneumoniae ATCC 49619 Range 0.008-0.03 ug/ml	<0.008			
	0.008	7	18	1
	0.015	33	22	37
	0.03		1	3
	>0.03	1		
H. influenzae ATCC 49247 Range 0.002-0.008 ug/ml	<0.002			
	0.002			
	0.004	37		38
	0.008	3		1
	>0.008			1

Quality control was performed at both sites using both the manual read method and the Autoread method. The Autoreads again had a trend to a more susceptible reading than the manual readings. This was more apparent at one site.

Nephelometer was used at each site to standardize the inoculum and it was calibrated each time it was switched on.

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
A clinical study was performed at two sites with the Sensititre® test panels and compared to the NCCLS broth reference method. The *S. pneumoniae* and the *H. influenzae* isolates were read by the manual method of reading while the *S. pneumoniae* isolates were also read using the Autoreader.

S. pneumoniae data manual reading

	total	**EA**	**%EA**	**Total evaluable**	**EA of evaluable**	**%EA**	**CA**	**%CA**	**#R**	**min**	**maj**	**vmj**
Clinical	234	232	99.1	234	232	99.1	230	98.3	3	4	0	0
Challenge	54	54	100	54	54	100	54	100	0	0	0	0
Combined	288	288	99.3	288	286	99.3	284	98.6	3	4	0	0

The *S. pneumoniae* Autoread results were very similar to the manual readings with acceptable EA, CA and error rates for both methods of reading. One observation of the results was the difference in the trending of the results as compared to the reference method. The

manual results trended to a slightly more resistant result (one well) while the Autoreads trended to a slightly more susceptible reading (one well) than the reference method.

H. influenzae data manual readings

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	212	207	97.6	208	203	97.6	212	100	0	0	0	0
Challenge	50	49	98	50	49	98	50	100	0	0	0	0
Combined	262	256	97.7	258	252	97.7	262	100	0	0	0	0

EA-Essential Agreement
CA-Category Agreement
R-resistant isolates
maj-major discrepancies
vmj-very major discrepancies
min- minor discrepancies

Evaluable results are those that fall within the test range of the reference method and could also be on-scale with the new device if within the plus/minus one well variability. EA is when there is agreement between the reference method and the Sensititre® result within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the Sensititre® result.

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   S. pneumoniae = ≤ 0.12 (S), 0.25 (I), ≥ 0.5 (R)
   Haemophilus influenzae ≤ 0.12 (S) The current absence of data on resistant strains precludes defining any results other than "Susceptible". Strains yielding MIC results suggestive of a "nonsusceptible" category should be submitted to a reference laboratory for further testing.

M. Conclusion:

The reproducibility, quality control results and overall performance appears to be acceptable although the recommendations as described in the "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" were not used in the design and evaluation of the study. The addition of an additional site would have added more diversity to the selection of isolates and also provide a more statistical valid reproducibility design. The appropriate control organisms are included in the labeling and are the same as those recommended in the NCCLS M7-(M100-S13) document. This performance as compared to a standard method demonstrates substantial equivalency to the predicate.